

SEP - 9 1996

K961023

## 510(k) SUMMARY

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### 1.1 Company Identification

Acculmage, Inc.  
1849 Old Bayshore Blvd.  
Burlingame, CA 94010  
(415) 692-8550

### 1.2 Official Correspondent

Gary J. Allsebrook  
Regulatory Affairs

### 1.3 Date of Submission

March 12, 1996

### 1.4 Device Name

Classification Name:	90LLZ, System, Image Processing
Common/Usual Name:	Image Processing Workstation
Proprietary Name:	Acculmage, Inc. Image Display Processor

### 1.5 Substantial Equivalence

Cemax VIPStation and/or Software      K945188, 2-Aug.-95

### 1.6 Device Description and Intended Use

The intended use of this software package is to render 3-dimensional images from a series of Computer Tomography cross sectional images. The software is usable on either desktop or laptop standard PC" off-the-shelf" hardware configurations. The hardware (PC workstations) may be supplied by either the end-user or by Acculmage. The Acculmage software processes and displays digital image data obtained in either DICOM 3.0, ACR-NEMA 2.0 format or in Imatron Proprietary format. System options include the ability to input data either through a standard Ethernet

K961023

connection or through the UPOW port of the Imatron C100 and C150 series of Ultrafast Electron Beam CT Scanners.

## 1.7 Software Development

AccuImage certifies that the Image Display Processor software is designed, developed, tested and validated according to written procedures. These procedures identify individuals within the organization responsible for developing and approving product specifications, coding and testing, validation testing and field maintenance. The software used in this product is used for camera control only and does not affect the image.

## 1.8 Substantial Equivalence Comparison Chart

Comparison Table

Feature	AccuImage AIDP2.1	Cemax VIP
Network Connectivity	General Purpose Interface Protocol (GPIB IEEE488)	Ethernet (TCP/IP), MegaLink
Computer Platform	Pentium/Win-95	Sun Sparc/SunOS
Image Format In	Imatron Proprietary ACR NEMA 2.0 DICOM 3.0	Imatron Proprietary ACR NEMA 2.0
Image Format Out	BMP	TIFF
Image Archive	IDE Disk drive, 1+ gig	SCSI Disk drive, 1+ gig
Image Display	Color/greyscale, CRT or Laptop LCD Up to 512x512, 12-bits	Color/greyscale, CRT Up to 1024x1024, 12 bits
Image Processing	Window/level, false color Zoom, variable Filter: edge, sharpen, smooth Cine display	Same
Image Edit	Manual segmentation by drawing a contour. Segmentation by CT-number threshold.	Same
Volume Rendering	Max or Min Intensity Projection (MIP, MinIP) Surface rendered Depth encoded surface Quick Mip Sliding Slab MIP	Max. Intensity Projection (MIP) Surface rendered